## REMARKS

Claims 1 through 3 have been cancelled. New Claims 4 through 6 have been added.

Note that on July 18, 2001, the undersigned had a telephone conversation with Supervisory Examiner Geist, who agreed that this Divisional Application should be filed to obtain examination and entry of Claims 4-6, as requested in the Amendment mailed by Applicant on March 13, 2001, in Response to the Office Action of December 19, 2000 in the co-pending Application Serial No. 09/265,640.

The foregoing Preliminary Amendment is submitted to correct minor typographical errors appearing in the Application. In particular, the chemical name of the compound taurolidine has been changed to provide that it is a 1,1-dioxide (the Examiner will note that a similar request was made in Applicant's co-pending Application Serial No. 09/266,095).

In addition, a minor change has been made to page 3, line 7, to correct another typographical error, and page 10, line 17 has been amended as requested by the Examiner in paragraph 4 of the Office Action of March 16, 2000 in the Patent Application. It is respectfully submitted that no new matter has been added by the Amendments and entry thereof is deemed proper and is respectfully requested.

New claims 4-6 cover a method for the prevention of the transfer of plasmid materials from a vancomycin resistant strain of bacteria to another, different strain of bacteria by administering taurolidine to a warm blooded animal. Support for new claim 4 can be found in the specification in the paragraph bridging pages 3 and 4 read in conjunction with the paragraph bridging pages 8 and 9 and the first paragraph on page 9 as well as the examples provided in the present Application. Entry of the Amendment is therefore deemed proper and respectfully requested.



Referring to paragraph 6 of the prior Office Action of December 19, 2000, in parent case Serial No. 09/265,640, it is noted that Claim 2 has been provisionally rejected under 35 U.S.C. Section 101 as claiming the same invention as that of claim 2 of co-pending Application No. 09/151,885. Applicants submit that the amendment to the claims is such that new claims 4-6 describe a different invention than that of Applicant's co-pending Application and therefore the double patenting rejection under 35 U.S.C. Section 101 should be withdrawn.

In the prior Office Action of December 19, 2000, in the parent case, Claims 1 and 3 stand provisionally rejected for obviousness type double patenting over claims 1 and 3 of co-pending application No. 09/151,885 and 09/266,215. It is respectfully submitted that these rejections should be withdrawn in consideration of this Preliminary Amendment adding new Claims 4-6, and cancelling Claims 1-3.

Version with markings to show changes made:

## ABSTRACT

The use of 4,4-methylenebis (tetrahydro-1,2,4-thiadiazine-1,[2-dioxide]1-dioxide) in the prevention and control of the development of antibiotic drug resistance in staphylococcus aureus bacteria and in the prevention of bacteria-to-bacteria transfer of genes capable of resisting antibiotics is disclosed.

Marked-up version of third paragraph on page 2:

Specifically, the present invention relates to the use of 4,4'-methylenebis(tetrahydro-1,2,4-thiadiazine-1,[2-dioxide] 1-dioxide) known generically as taurolidine to treat antibiotic drug (e.g. gentamicin, methicillin and vancomycin) resistant bacterial infections, nosocomial infections and/or eradication of these organisms from an individual acting as a "carrier" for these organisms.

Marked-up version of last paragraph on page 2 extending into page 3:

The development of antimicrobial agents has, without questions, been one of the crowning achievements of medical science in the latter half of the twentieth century. However, despite the fact that dozens of classes of compounds have been developed, microorganisms, especially bacteria, have developed resistance to virtually every agent which has been subjected to extensive clinical use. As we approach the end of the twentieth century, there has been a precipitous decline in the development of new antimicrobial agents. There are several reasons

for this including the fact that most of the easy targets that allow selective toxicity for antimicrobial agents have been discovered and the fact that it is increasingly expensive to bring a new antimicrobial agent from discovery to the marketplace. There is, however, a major need for discovery of novel classes of antimicrobial agents to which multi-resistant bacteria remain susceptible. Taurolin is such a novel new antimicrobial agent. It has a formulation which comprises taurolidine [(4~-] (4-methylene bis (tetrahydro-1,2,4 thiadiazine 1, 1 dioxide). A derivative of aminosulphonic acid taurineamide, this is a novel bactericidal agent that has a unique spectrum of antimicrobial activity that, in preliminary tests, has included Gram-positive and Gram-negative bacteria and fungi. It has been subjected to early clinical trials and it appears to have useful activity in vivo when administered by intravenous or intraperitoneal routes. This compound also has the ability to neutralize endotoxin in vitro and it also exhibits marked anti-adherence properties in vitro.

Marked-up version of second full paragraph on page 10, beginning on line 13:

As noted above, taurolidine's mechanism of action unlike that of known antibiotics is based on chemical reaction. While not being bound by any theory, during the metabolism of taurolidine to taurinamide and ultimately taurine and water, methylol groups are liberated which chemically react with the mureins in the bacterial [cell walls this] . This results in the denaturing of the complex polysaccharide and liposaccharide components of the bacterial cell wall as well as changing the double standard DNA of the plasmid to a denatured or single stranded DNA.

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It is believed that Claims 4-6 are patentable, and in condition for allowance. Accordingly, it is respectfully requested that the claims be examined, allowed, and the case passed to issue.

Respectfully submitted,

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